Complete Summary

GUIDELINE TITLE

Benign prostatic hyperplasia.

BIBLIOGRAPHIC SOURCE(S)

Finnish Medical Society Duodecim. Benign prostatic hyperplasia. In: EBM Guidelines. Evidence-Based Medicine [CD-ROM]. Helsinki, Finland: Duodecim Medical Publications Ltd.; 2004 Apr 10 [Various]. [9 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Benign prostatic hyperplasia

GUIDELINE CATEGORY

Diagnosis
Evaluation
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Urology

INTENDED USERS

Health Care Providers
Physicians

GUIDELINE OBJECTIVE(S)

Evidence-Based Medicine Guidelines collect, summarize, and update the core clinical knowledge essential in general practice. The guidelines also describe the scientific evidence underlying the given recommendations.

TARGET POPULATION

Men with suspected or confirmed benign prostatic hyperplasia

INTERVENTIONS AND PRACTICES CONSIDERED

Primary Investigations

1. Assessment of signs and symptoms
2. Symptoms questionnaire (e.g., DAN-PSS-1 [Danish Prostatic Symptom Score])
3. Writing down details associated with voiding
4. Touch per rectum
5. Urinalysis
6. Serum creatinine
7. Serum prostate-specific antigen (PSA)
8. Residual urine volume as determined by ultrasonography or catheterization
9. Palpation of the prostate
10. Cystoscopy
11. Consultation with a specialist if indicated

Investigations Performed by Urologist

1. Urine flow measurement
2. Transrectal ultrasonography
3. Cystometry and pressure-flow examination
4. Urethrocystography
5. Urography
6. Prostatic biopsy

Treatment

1. Watchful follow-up (no treatment)
2. Drug treatment
    - Combination of finasteride and alpha$_1$-blockers
    - Alpha$_1$-blockers, such as tamsulosin, alfuzosin, terazosin, or prazosin
    - Finasteride
3. Surgical and other invasive treatments
    - Transurethral resection of the prostate (TURP)
    - Transurethral incision of the prostate (TUIP)
    - Open prostatectomy
    - Laser prostatectomy and radiofrequency ablation
    - Thermotherapy (microwave treatment)
    - Stent or spiral
4. Percutaneous cystostomy or catheterization

5. Repeated catheterization
6. A silicon catheter with the balloon filled with hypertonic (5%) saline
7. Pygeum africanum

Follow-up Treatment after Transurethral Resection of the Prostate

1. Urine bacterial culture
2. Antibiotics (if bacterial infection is detected)
3. Pelvic floor exercises for stress incontinence
4. Oxybutynin or tolterodine for urge incontinence and nocturia

MAJOR OUTCOMES CONSIDERED

- Effect of treatment measures on factors such as symptoms, peak urinary flow, volume of residual urine, urinary flow rate, nocturia, size of prostate, and obstruction
- Adverse effects of treatment
- Cost-effectiveness of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The evidence reviewed was collected from the Cochrane database of systematic reviews and the database of abstracts of reviews of effectiveness (DARE). In addition, the Cochrane Library and medical journals were searched specifically for original publications.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

A. Strong research-based evidence. Multiple relevant, high-quality scientific studies with homogenic results.

B. Moderate research-based evidence. At least one relevant, high-quality study or multiple adequate studies.
C. Limited research-based evidence. At least one adequate scientific study.
D. No research-based evidence. Expert panel evaluation of other information.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The levels of evidence [A-D] supporting the recommendations are defined at the end of the "Major Recommendations" field.

Aims

- The diagnosis of benign prostatic hyperplasia is based on symptoms and basic investigations. Other causes of voiding disturbances (prostate cancer in particular) are excluded.
- Conditions requiring surgical management are recognized.
- Follow-up alone or drug therapy are good options in patients with relatively mild symptoms and no complications of urinary tract stricture.

Symptoms

- Retention symptoms
  - Extraordinary urinary frequency
  - Nocturia
  - Urinary urgency
  - Urge incontinence
- Voiding symptoms
  - Difficulty in the initiation of voiding
  - Poor urine flow
  - Need to strain while voiding
  - Discontinued voiding
  - Feeling of inadequate bladder emptying
  - Urinary retention

Primary Investigations

- Symptom questionnaire
  - The most commonly used questionnaire is the DAN-PSS-1 (Danish Prostatic Symptom Score). The severity of lower urinary tract symptoms can be classified as follows:
    - score <7 points = mild
    - score 8–18 = moderate
    - score >18 = severe
  - The questionnaire is useful in the assessment of mild symptoms when decisions are made between follow-up, drug treatment, and surgery.
- Writing down details associated with voiding
- Palpation of the prostate by touch per rectum
- Urinalysis
- Serum creatinine
- Serum prostate-specific antigen (PSA)
- Residual urine volume is determined by ultrasonography (see the National Guideline Clearinghouse [NGC] guideline summary of the Evidence-Based Medicine [EBM] guideline Determining the Volume of Residual Urine by Ultrasonography) (or, if ultrasonography is not available, by catheterization). Ultrasonography is useful in the determination of prostatic size (calculated with the same equation as residual urine volume), shape, and eventual hydronephrosis.
- Differential diagnosis, see table below.

Table: Differential Diagnosis on Benign Prostatic Hyperplasia

Condition or disease	History or finding
Prostate cancer	Finding in touch per rectum, elevated serum PSA concentration
Urinary bladder cancer	Haematuria, abnormal cytological finding
Bladder calculi	Haematuria, ultrasonography finding

Condition or disease	History or finding
Cicatricial urethral stricture	Box-shaped flow curve
Stricture of the bladder neck	Earlier invasive treatment
Dyssynergy of the striated sphincter muscle	Small prostate gland, disturbing symptoms associated with voiding
Prostatitis	Tender prostate gland
Overactive bladder	Urgency with possible urge incontinence

Indications for Specialist Consultation

Indications for Diagnostic Investigations by the Urologist

- The patient is below 50 years of age.
- The palpation findings of the prostate are suspicious (nodules).
- Serum PSA is above 10 micrograms/L (above 3 micrograms/L in patients under 65 years of age).
    - If the serum total PSA concentration is in the range of 3 to 10 micrograms/L, measuring free/total PSA ratio is recommended. If this value is under 0.15, the probability of prostatic cancer is increased (Walsh, 1996) and a urologist should be consulted.
    - Touch per rectum before determination of serum PSA level does not influence the result.
- Rapidly developing symptoms
- Haematuria (cystoscopy)
- Diabetics who may have neuropathy
- History of pelvic surgery or irradiation
- Neurological disease or injury affecting the function of the urinary bladder
- Necessary medication affecting the function of the urinary bladder
- Lower abdominal pain as the main symptom
- Discrepancy between symptoms and findings
- The investigations performed by the urologist usually include:
    - urine flow measurement
    - transrectal ultrasonography
- and if necessary also
    - cystometry and pressure-flow examination (recommended before deciding on surgery if the peak flow is >10 mL/s and also when there is a discrepancy between symptoms and findings or the patient has undergone surgery of the lower urinary tract)
    - urethrocystography
    - urography
    - prostatic biopsies
    - cystoscopy

Surgical Treatment Is Indicated in the Following Cases:

- Urinary retention, overflow incontinence, or repeatedly more than 300 mL of residual urine
- Severe symptoms (>18 points)
- Dilatation of the upper urinary tract
- Impairment of renal function
- Recurrent macrohaematuria
- Urinary tract infections
- Bladder calculi
- Severe or moderate symptoms in a patient who wants rapid relief or if satisfactory results have not been obtained with other treatments

Conservative Treatment

Follow-up

- As the symptoms of prostate hyperplasia vary greatly and the course of the disease in an individual cannot be predicted, follow-up is a suitable approach in patients with mild symptoms. Also in moderate symptoms, follow-up can be the initial approach if the symptoms do not essentially affect the quality of life and complications have not developed.
- Follow-up includes explaining to the patient the nature of the disease and carrying out basic investigations annually or when symptoms have changed. Opportunistic follow-up during other encounters in primary care is one method of screening.

Drug Treatment

- Although the effectiveness of drug treatment is not as good as that of surgery it is often sufficient for reducing or alleviating the symptoms.
- When deciding on the treatment, cost-effectiveness should also be evaluated (i.e., when would invasive therapy, which usually gives complete cure, cost less and be more convenient for the patient than drug therapy continuing for years [for example, to avoid one invasive treatment, 20 men have to be treated with finasteride for 4 years]). Transurethral resection is more cost-effective than drug treatment.
- Patients on drug treatment should be followed up regularly at 6- to 12-month intervals to detect complications resulting from urethral obstruction.
- Drug treatment is contraindicated if the patient has obstructive symptoms (see indications for surgery above).
- The size of the prostate and total serum PSA determine the selection of the therapy (Boyle, Gould, & Roehrborn, 1996; DARE-961572, 1999) [C]. If the prostate is not markedly enlarged on palpation or in ultrasonography (<40 g) and PSA is <1.5 micrograms/L the first choice is an $alpha_1$-blocker (e.g., tamsulosin) (Lepor et al., 1996; Boyle, Gould, & Roehrborn, 1996). If the prostate is markedly enlarged or PSA is >1.5 micrograms/L, either finasteride (Wilde & Goa, 1999; DARE-990978, 2000) [A] or an $alpha_1$-blocker can be used.
- A combination of finasteride and $alpha_1$-blocker alleviates symptoms more effectively than either drug alone (McConnell et al, 2003) [B].

$Alpha_1$-blockers

- Tamsulosin 0.4 mg x 1 ("Tamsulosin for benign prostatic hyperplasia," 2003) [A], alfuzosin 5 mg x 2 (sustained release 10 mg × 1), and prazosin
- $Alpha_1$-blockers decrease symptoms, increase peak urinary flow, and reduce the volume of residual urine significantly more than placebo.
- The effect of $alpha_1$-blockers is seen rapidly, and it has been shown to continue for several years.
- The patients should be followed up initially at 1- to 3-month intervals.
- The side effects include dizziness, postural hypotension, and retrograde ejaculation. With selective tamsulosin and alfuzosin the risk of hypotension is lower.

Finasteride

- The dose is 5 mg x 1.
- The symptoms are alleviated, the urine flow is increased, and the obstruction is decreased (Wilde & Goa, 1999; DARE-990978, 2000) [A].
- The effect is at its best in patients with large prostates (Boyle, Gould, & Roehrborn, 1996; DARE-961572, 1999) [C] (In two placebo-controlled studies the average prostatic sizes were 60 and 47 mL.) (Walsh, 1996).
- The effect starts slowly, sometimes as late as 6 months after the onset of treatment. If no effect is observed in 6 months, the indications for surgery should be reconsidered.
- The drug decreases prostatic size, but the prostate returns to its original size a few months after discontinuation of treatment.
- Impotence may occur as an adverse effect.

<u>Surgical and Other Invasive Treatments</u>

- Transurethral resection of the prostate (TURP)
    - The only treatment for complicated prostatic hypertrophy and the best documented treatment for uncomplicated disease
    - Results very seldom in erectile dysfunction (though in most cases already before operation), almost always retrograde ejaculation.
- Transurethral incision of the prostate (TUIP)
    - Suitable for patients with prostates <30 mL and no prominent median lobe
- Open prostatectomy
    - Rarely used nowadays (prostate >100 mL)
- Laser prostatectomy (Larizgoitia & Pons, 1999; DARE-994093, 2001) [B] and radiofrequency ablation
    - Long-term results are not available. No histological specimens are obtained.
- Thermotherapy (microwave treatment)
    - Alleviates irritative symptoms
    - Long-term results are not available.
- Stent or spiral
    - Can be used in selected cases in patients with a poor general condition

<u>Catheter</u>

- Percutaneous cystostomy is indicated in patients with urinary retention waiting for surgery.

- In selected cases repeated catheterization can be used (preferably by the patient himself).
- A silicon catheter with the balloon filled with hypertonic (5%) saline can be used, but percutaneous cystostomy is preferred.

Treatment after Transurethral Resection of the Prostate (TURP)

- Urine bacterial culture should be taken routinely 4 to 6 weeks after the operation to detect bacteriuria, and always if a urinary tract infection is suspected (pyuria and haematuria may occur as long as 3 months after the operation).
- If bacterial growth is detected, antibiotics are indicated.
- Stress incontinence may be alleviated within 1 year; exercises of pelvic floor muscles may help.
- Oxybutynin or tolterodine can be used for the treatment of urge incontinence and nocturia.

Related Evidence

- Pygeum africanum may have some efficacy for benign prostatic hyperplasia ("Pygeum africanum for benign prostatic hyperplasia," 2002) [C].
- Terazosin has similar efficacy to other alpha-blockers in prostatic hyperplasia. Adverse effects were generally mild but more frequent than with other alpha-blockers (Wilt et al., 2002) [A].
- Laser techniques appear to be a useful alternative to transurethral resection of the prostate for treating benign prostatic obstruction (Hoffman, MacDonald, & Wilt, 2004) [B].

Definitions:

Levels of Evidence

A. Strong research-based evidence. Multiple relevant, high-quality scientific studies with homogenic results.
B. Moderate research-based evidence. At least one relevant, high-quality study or multiple adequate studies.
C. Limited research-based evidence. At least one adequate scientific study.
D. No research-based evidence. Expert panel evaluation of other information.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Concise summaries of scientific evidence attached to the individual guidelines are the unique feature of the Evidence-Based Medicine Guidelines. The evidence summaries allow the clinician to judge how well-founded the treatment recommendations are. The type of supporting evidence is identified and graded for select recommendations (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnostic evaluation and treatment of benign prostatic hyperplasia

Subgroups of Patients Within Target Population Most Likely to Benefit

Finasteride is most effective in men with large prostates.

POTENTIAL HARMS

- Side effects of alpha$_1$-blockers include dizziness, postural hypotension, and retrograde ejaculation.
- Finasteride may cause impotence.
- Transurethral resection of the prostate may cause urinary tract infection, stress incontinence, urge incontinence, nocturia, and very seldom, erectile dysfunction.

CONTRAINDICATIONS

CONTRAINDICATIONS

Drug treatment is contraindicated if the patient has obstructive symptoms.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Finnish Medical Society Duodecim. Benign prostatic hyperplasia. In: EBM Guidelines. Evidence-Based Medicine [CD-ROM]. Helsinki, Finland: Duodecim Medical Publications Ltd.; 2004 Apr 10 [Various]. [9 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Apr 30 (revised 2004 Apr 10)

GUIDELINE DEVELOPER(S)

Finnish Medical Society Duodecim - Professional Association

SOURCE(S) OF FUNDING

Finnish Medical Society Duodecim

GUIDELINE COMMITTEE

Editorial Team of EBM Guidelines

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Author: Editors

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Benign prostatic hyperplasia. Helsinki, Finland: Duodecim Medical Publications Ltd; 2002 Mar 22. Various p.

GUIDELINE AVAILABILITY

This guideline is included in a CD-ROM titled "EBM Guidelines. Evidence-Based Medicine" available from Duodecim Medical Publications, Ltd, PO Box 713, 00101 Helsinki, Finland; e-mail: info@ebm-guidelines.com; Web site: www.ebm-guidelines.com.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- EBM guidelines. Evidence-based medicine. Helsinki, Finland: Duodecim Medical Publications, Ltd. 2004. [CD-ROM]
- EBM guidelines. Web site: www.ebm-guidelines.com.

Available from: Duodecim Medical Publications, Ltd, PO Box 713, 00101 Helsinki, Finland; e-mail: info@ebm-guidelines.com; Web site: www.ebm-guidelines.com.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on August 28, 2001. The information was verified by the guideline developer as of October 26, 2001. This summary was updated by ECRI on December 9, 2002, December 29, 2003, and July 15, 2004.

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